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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/381,497	02/17/00	FITZGERALD D	015280-31710

HM12/0830

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EXAMINER	
HELMS, L	

ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 08/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/381,497	FitzGerald et al
Examiner	**Group Art Unit**
Larry R. Helms Ph.D.	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *NONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-39* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-39* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10 and 33-36, drawn to an antiCD22 antibody and immunoconjugates, classified in class 530, subclass 391.7.

   II. Claims 11-17 and 20-21, drawn to nucleic acids, expression cassette, and host cell, classified in class 536, subclass 23.1.

   III. Claim 18, drawn to a VL sequence, classified in class 530, subclass 350.

   IV. Claim 19, drawn to a VH sequence, classified in class 530, subclass 350.

   V. Claims 22-32, drawn to a method for inhibiting the growth of a malignant B-cell, classified in class 424, subclass 179.1.

   VI. Claims 37-39, drawn to a method for detecting the presence of CD22 protein in a biological sample, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibody and conjugates of Group I, the nucleic acids and host cell of Group II, the VL of Group III, and the VH of Group IV are all structurally and chemically different from each other. The nucleic acid is made by nucleic

acid synthesis, while the VL and VH are made by translation of mRNA or chemical synthesis, and the antibody is raised by immunization. Furthermore, the nucleotide can be used for hybridization screening and the antibody can be used to immunopurify the antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-IV are patentably distinct.

The methods of Inventions V and VI differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites expressing of the heat shock protein; Invention IV recites treatment by administering a heat shock protein; Invention V recites treatment using an antagonist of a heat shock protein; Invention VI recite a method of diagnosis by screening for DNA mutations and Invention VII recites screening for antagonists of the heat shock protein. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I and IV-VII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The methods of Inventions V and VI differ in the method objectives. Invention V recites a method for inhibiting the growth of a malignant B-cell and Invention VI recites a method for detecting the presence of CD22 protein in a biological sample. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and

would require the consideration of different patentability issues. Thus Inventions V and VI are separate and distinct in having method objectives are patentably distinct.

Inventions I and (V-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in either of the materially different methods of Groups V and VI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

SHEELA HUFF
PRIMARY EXAMINER